

## **REMARKS**

In response to the Office Action dated July 12, 2006, Applicants respectfully submit the present Amendment and Remarks, and reconsideration is respectfully requested.

### **Amendment to Claims**

Applicants respectfully submit that claims 1-8, 12 and 13 have been cancelled and claim 9-11, 14 and 15 have been amended. Support for these amended claims can be found throughout the specification, particularly in the original claims and in the examples. Specifically, claims 9 has been amended to replace the term "preventing" with "treating" and incorporating the feature of the cancelled claims, particularly cancelled claims 1 and 2. Claims 10 and 11 have also been amended to include the feature of the cancelled claims, particularly cancelled claims 4 and 5 respectively. Claim 15 has been amended to read as a dependent claim of claim 14.

New claims 16-19 have been added. Support for these new claims can be found throughout the specification and original claims, particularly cancelled claims 4 and 5.

No new matter has been added. Hence, Applicants respectfully request consideration and entry of these claims.

Claims 9-11, 14-19 are currently pending in this application.

### **Claimed Invention**

The present invention, as claimed, recites a method for treating infectious diseases of a virus belonging to the Coronavirus family or Flavivirus family, which comprises administering at least one member selected from the group consisting of reduced and oxidized glutathiones, pharmaceutically

acceptable salts thereof. The present invention also recites a method for treating infectious diseases of a virus belonging to the Coronavirus family or Flavivirus family, which comprises administering reduced or oxidized glutathione, or a pharmaceutically acceptable salt thereof, and catechin. In addition, the present invention recites a method for treating infectious diseases of a virus belonging to the Coronavirus family or Flavivirus family for non-human animals, which comprises administering a nasal aerosol comprising at least one member selected from the group consisting of reduced and oxidized glutathiones, and pharmaceutically acceptable salts thereof, held at from 30°C to 50°C into the nose of non-human animals.

**Summary of the Office Action**

In the Office Action dated July 12, 2006, the Examiner rejects claims 1-15 under 35 U.S.C. 112, first paragraph, alleging the specification, while being enabling for treatment of Flavivirus or Coronavirus, does not reasonably provide enablement for prevention of Flavivirus or Coronavirus as set forth on pages 2-5 of the Office Action. The Examiner also rejects claims 12 and 13 as not setting forth any steps involved in the method/process, as being unclear what method/process applicant is intending to encompass.

At page 5 of the Office Action, the Examiner rejects claims 1-11 and 14-15 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At page 6 of the office action, the Examiner also rejects claims 12 and 13 under 35 USC 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a

process.

At page 7 of the Office Action, the Examiner rejects claims 1 and 4-8 under 35 USC 102(b) as being anticipated by Woong et al. (DNA and Cell Biology, Vol. 22(3)). Also at page 7 of the Office Action, the Examiner rejects claims 1, 4-6 and 14 under 35 USC 102(b) as being anticipated by Saito et al. (Microbiol. Immunol. Vol. 46(4)).

In addition, at pages 7 and 8 of the Office Action, the Examiner rejects claims 1, 4-5 and 14 under 35 USC 102(b) as being anticipated by Clark et al. (Veterinary Microbiology Vol. 63). Also at page 8 of the Office Action, the Examiner has rejected claims 1 and 3-8 under 35 USC 102(b) as being anticipated by claims 1-7 of U.S. Patent No. 6,013,632. The Examiner also rejects claims 1 and 3-8 under 35 USC 102(b) as being anticipated by claims 1-3 of U.S. Patent No. 6,107,281 at page 8 of the Office Action.

Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-3 of U.S. Patent No. 6,107,281. Claims 1 and 3-8 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-7 of U.S. Patent No. 6,013,632.

Finally, at pages 10 and 11 of the office action, the Examiner rejects claims 1-8 under 35 USC 103(a) as being unpatentable over claims 1-7 of U.S. Patent No. 6,013,632 in combination with claims 1-3 of U.S. Patent No. 6,107,281.

## **RESPONSE**

### **Rejections under 35 U.S.C. §112, 1<sup>st</sup> paragraph**

Claims 1 to 15 are rejected under 35 U.S.C. §112, 1<sup>st</sup> paragraph as failing to comply with the enablement requirement. The Examiner is alleging that the present claims contain subject matter which is not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner is alleging that although the specification is enabling for treatment of Flavivirus or Coronavirus, it does not reasonably provide enablement for preventing Flavivirus or Coronavirus.

Applicants respectfully point out that the present claims have been amended to recite methods for treating Flavivirus or Coronavirus. Further, claims 1-8, 12 and 13 have been cancelled. Therefore, this rejection has been obviated.

With regard to the Examiner's rejection of claims 12 and 13 for not setting forth any steps involved in the method/process, as being unclear what method/process applicant is intending to encompass, Applicants respectfully point out that claims 1-8, 12 and 13 have been cancelled. Therefore, this rejection has been obviated.

In view of the amendment and cancellation of the claims, Applicants respectfully request reconsideration and withdrawal of this rejection.

### **Rejection under 35 U.S.C. §112, 2<sup>nd</sup> paragraph**

Claims 1-11 and 14-15 are rejected under 35 u112, 2<sup>nd</sup> paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the

Examiner alleges that “[c]laim 1 requires one compound selected from the Markush group to be in the composition[;] however, claim 2 requires more than one compound from the Markush group yet claim 2 depends directly from claim 1.” The Examiner also asserts that “[i]t is unclear as to whether claim 1 should be open to one or more members of the Markush group as cited in claim 14. With regard to claims 3-11 and 15, the Examiner rejects these claims for depending on claims 1 and 14, respectively.

In response to the Examiner’s assertion, Applicants respectfully point out that claims 1-8 have been cancelled and claim 9 has been amended to read as an independent claim. Claims 14 and 15, as amended do not depend directly or indirectly from claim 1. Therefore, this rejection has been obviated.

In view of the amendment and cancellation of the claims, Applicants respectfully request reconsideration and withdrawal of this rejection.

**Rejection under 35 U.S.C. §101**

At page 6 of the office action, the Examiner also rejects claims 12 and 13 under 35 USC 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process.

In response, Applicants respectfully point out that claims 12 and 13 have been cancelled. Therefore, this rejection has been obviated.

In view of the cancellation of the claims, Applicants respectfully request reconsideration and withdrawal of this rejection.

**Rejections under 35 U.S.C. §102**

The Examiner has made five different rejections under U.S.C. §102(b).

**Wong et al.**

At page 7 of the Office Action, the Examiner rejects claims 1 and 4-8 under 35 USC 102(b) as being anticipated by Woong et al. (DNA and Cell Biology, Vol. 22(3)). The Examiner contends that Woong et al. “teach green tea constituent, (-)-epigallocatechin (EGCG) in a pharmaceutical composition delivered via drinking EGCG in water. Further, the Examiner contends that Woong et al. teach that EGCG in water is for oral delivery. Therefore, the Examiner concludes that Woong et al. teach the claimed invention of claims 1 and 4-8.

In response, Applicants respectfully point out that claims 1 and 4-8 have been cancelled. Therefore, this rejection has been obviated.

In view of the cancellation of the claims, Applicants respectfully request reconsideration and withdrawal of this rejection.

**Saito et al.**

At page 7 of the Office Action, the Examiner rejects claims 1, 4-6 and 14 under 35 USC 102(b) as being anticipated by Saito et al. (Microbiol. Immunol. Vol. 46(4)). The Examiner contends that Saito et al. “teach the use of apple polyphenols, specifically fraction FAP2, 3 and 4, as being successful in suppression of Flavivirus in mouse models” as recited in claim 14. Further, the Examiner contends that “Saito et al. reads on composition comprising one member of the Markush group of claim 1 and 14, and anticipates the compositions of claims 4-6.”

Applicants respectfully point out that claims 1, 4-6 have been cancelled. In addition, claim 14 has been amended to recite a method for treating infectious diseases of a virus belonging to the Coronavirus family or

Flavivirus family, which comprises administering at least one member selected from the group consisting of reduced and oxidized glutathiones, pharmaceutically acceptable salts thereof. "Catechin" has been removed from amended claim 14.

Saito et al. neither teach nor suggest a method for treating infectious diseases of a virus belonging to the Coronavirus family or Flavivirus family, which comprises administering at least one member selected from the group consisting of reduced and oxidized glutathiones, and pharmaceutically acceptable salts thereof as claimed in amended claim 14.

Therefore, Applicants respectfully request reconsideration and withdrawal of this rejection.

**Clark et al.**

At pages 7 and 8 of the Office Action, the Examiner rejects claims 1, 4-5 and 14 under 35 USC 102(b) as being anticipated by Clark et al. (Veterinary Microbiology Vol. 63). The Examiner asserts that "Clark et al. teach the use of theaflavin from tea for [the] treatment of Coronavirus infections. Therefore, the Examiner concludes that "Clark et al. reads on compositions comprising one member of the Markush group of claims 1, 4-5 and 14.

Again, Applicants respectfully point out that claims 1, 4-5 have been cancelled. In addition, claim 14 has been amended to recite a method for treating infectious diseases of a virus belonging to the Coronavirus family or Flavivirus family, which comprises administering at least one member selected from the group consisting of reduced and oxidized glutathiones, pharmaceutically acceptable salts thereof. "Catechin" has been removed from amended claim 14.

Clark et al. neither teach nor suggest a method for treating infectious diseases of a virus belonging to the Coronavirus family or Flavivirus family, which comprises administering at least one member selected from the group consisting of reduced and oxidized glutathiones, and pharmaceutically acceptable salts thereof as claimed in amended claim 14.

Therefore, Applicants respectfully request reconsideration and withdrawal of this rejection.

**U.S. Patent No. 6,013,632**

A at page 8 of the Office Action, the Examiner has rejected claims 1 and 3-8 under 35 USC 102(b) as being anticipated by claims 1-7 of U.S. Patent No. 6,013,632 (the '632 patent). The Examiner contends that claims 1-7 of the '632 patent recite "a pharmaceutical composition comprising glutathione (reduced and oxidized, and pharmaceutical salts thereof) for oral, nasal, or rectal administration; wherein the composition can be delivered via lozenge, cough drop, oral rinse, drinking solution, and nasal drops and sprays." The Examiner also contends that the '632 patent teaches "antioxidants as part of the pharmaceutical composition, wherein the antioxidants are enumerated including catechin." Therefore, the Examiner concludes that the '632 patent teach the invention of claims 1 and 3-8.

In response, Applicants respectfully point out that claims 1 and 3-8 have been cancelled. Therefore, this rejection has been obviated.

In view of the cancellation of the claims, Applicants respectfully request reconsideration and withdrawal of this rejection.



**U.S. Patent No. 6,107,281**

A at page 8 of the Office Action, the Examiner has rejected claims 1 and 3-8 under 35 USC 102(b) as being anticipated by claims 1-3 of U.S. Patent No. 6,107,281 (the '281 patent). The Examiner contends that claims 1-3 of the '281 patent teach "methods of treatment comprising administration of pharmaceutical composition comprising glutathione (reduced and oxidized, and pharmaceutical salts thereof) for oral, nasal, or rectal administration." The Examiner also contends that the '281 patent teaches "antioxidants as part of the pharmaceutical composition, wherein the antioxidants are enumerated including catechin." Therefore, the Examiner concludes that the '281 patent teach the invention of claims 1 and 3-8.

In response, Applicants respectfully point out that claims 1 and 3-8 have been cancelled. Therefore, this rejection has been obviated.

In view of the cancellation of the claims, Applicants respectfully request reconsideration and withdrawal of this rejection.

**Double Patenting Rejections**

The Examiner has made two different rejections the judicially created doctrine of obviousness-type double patenting.

**U.S. Patent No. 6,107,281**

Claims 1-7 have been rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-3 and U.S. Patent No. 6,107,281.

In response, Applicants respectfully point out that claims 1-3 have been cancelled. Therefore, this rejection has been obviated.

In view of the cancellation of the claims, Applicants respectfully request reconsideration and withdrawal of this rejection.

**U.S. Patent No. 6,013,632**

Claims 1 and 3-8 have been rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-7 of U.S. Patent No. 6,013,632.

In response, Applicants respectfully point out that claims 1-3 have been cancelled. Therefore, this rejection has been obviated.

In view of the cancellation of the claims, Applicants respectfully request reconsideration and withdrawal of this rejection.

**Rejection under 35 USC §103(a)**

At pages 10 and 11 of the office action, the Examiner rejects claims 1-8 under 35 USC 103(a) as being unpatentable over claims 1-7 of U.S. Patent No. 6,013,632 (the '632 patent) in combination with claims 1-3 of U.S. Patent No. 6,107,281 (the '281 patent). The Examiner contends that the '632 patent recite "a pharmaceutical composition comprising glutathione (reduced and oxidized, and pharmaceutical salts thereof) for oral, nasal, or rectal administration; wherein the composition can be delivered via lozenge, cough drop, oral rinse, drinking solution, and nasal drops and sprays." The Examiner also contends that the '632 patent teaches "antioxidants as part of the pharmaceutical composition, wherein the antioxidants are enumerated including catechin."

With regard to the '281 patent, the examiner contends that this patent teach "methods of treatment comprising administration of pharmaceutical composition comprising glutathione (reduced and oxidized, and

pharmaceutical salts thereof) for oral, nasal, or rectal administration.” The Examiner also contends that the ‘281 patent teaches “antioxidants as part of the pharmaceutical composition, wherein the antioxidants are enumerated including catechin.”

Therefore, the Examiner concludes that it would have been obvious for one of skill in the art to make the claimed invention of claims 1-8.

Applicants respectfully point out that claims 1-8 have been cancelled. Therefore, this rejection has been obviated.

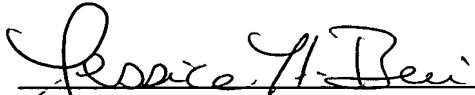
In view of the cancellation of the claims, Applicants respectfully request reconsideration and withdrawal of this rejection.

#### **CONCLUSION**

In light of the foregoing amendments and remarks, Applicants respectfully submit that the application is now in condition for allowance. Should any minor matter remain, or should the Examiner feel that an interview would expedite the prosecution of this application; the Examiner is invited to call the undersigned at his convenience.

To the extent necessary, Applicants petition for an extension of time under 37 CFR §1.136. Please charge any shortage in the fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account No. 01-2135 (Case No. 506.45841X00) and please credit any excess fees to such deposit account.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Jessica H. Bui", written over a horizontal line.

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